

IFW

Applicant's Docket No. U 014843-4

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent application  
of \_\_\_\_\_

Inventor(s)

for \_\_\_\_\_

Title of invention

OR

In re application of: Makoto TSUDA, et al

Serial No.: 10/676,289

Group No.: 1645

Filed: October 1, 2003

Examiner.:

For: SCREENING METHOD OF DRUG FOR TREATMENT OF NEUROPATHIC PAIN

Commissioner for Patents  
P. O. Box 1450  
Alexandria, VA 22313-1450

TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT  
WITHIN THREE MONTHS OF FILING OR  
BEFORE MAILING OF FIRST OFFICE ACTION (37 C.F.R. 1.97(b))

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Date: June 3, 2004

- \* Only the date of filing (§ 1.6) will be the date used in a patent term adjustment calculation, although the date on any certificate of mailing or transmission under § 1.8 continues to be taken into account in determining timeliness. See § 1.703(f). Consider "Express Mail Post Office to Addressee" (§ 1.10) or facsimile transmission (§ 1.6(d)) for the reply to be accorded the earliest possible filing date for patent term adjustment calculations.

**NOTE:** 37 C.F.R. 1.98(b):

- (1) *Each U.S. patent listed in an information disclosure statement must be identified by inventor, patent number, and issue date.*
- (2) *Each U.S. patent application published listed in an information disclosure statement shall be identified by applicant, patent application publication number, and publication date.*
- (3) *Each U.S. application listed in an information disclosure statement must be identified by the inventor, application number, and filing date.*
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- (5) *Each publication listed in an information disclosure statement must be identified by publisher, author (if any), title, relevant pages of the publication, date, and place of publication.*

**WARNING:** *No extension of time can be had under 37 C.F.R. § 1.36 (a) or (b) for filing an IDS. 37 C.F.R. § 1.97(f).*

**NOTE:** *The "filing date of a national application" under 37 C.F.R. 1.97(b) has two possible meanings. Where the filing is a direct one to the United States Patent & Trademark office, the filing is defined in 37 C.F.R. 1.53(b) as "the date on which: (1) A specification containing a description pursuant to § 1.71 and at least one claim pursuant to § 1.75; and (2) any drawing required by § 1.81(a), are filed in the Patent and Trademark Office in the name of the actual inventor or inventors as required by § 1.41." 37 C.F.R. 1.97(b)(1). On the other hand, an international application that enters the national stage occurs when the applicant has filed the documents and fees required by 35 U.S.C. § 371(c) within the periods set forth in § 1.494 or § 1.495. 35 U.S.C. § 371(c) requires the filing of the following: (1) the national fee; (2) a copy of the international application, unless already sent by the International Bureau, and an English translation if filed in another language; (3) amendments under PCT Article 19, with a translation into English if made in another language; (4) an oath or declaration; and (5) a translation into English of any annexes to the international preliminary examination report, if such annexes were made in another language. 37 C.F.R. 1.97(b)(2).*

### **IDENTIFICATION OF TIME OF FILING THE ACCOMPANYING INFORMATION DISCLOSURE STATEMENT**

The information disclosure statement submitted herewith is being filed within three months of the filing date of the application or date of entry into the national stage of an international application or before the mailing date of a first Office action on the merits, whichever event occurs last. 37 C.F.R. 1.97(b).

**NOTE:** *"No certification or fee is due when the filing is made within the above time period. It is advisable to ensure that no Office action has been mailed if the disclosure statement is delayed until after three months from filing."*

**NOTE:** *"An information disclosure statement will be considered to have been filed on the day it was received in the Office, or on an earlier date of a mailing if accompanied by a properly executed certificate of mailing under 37 C.F.R. 1.8, or Express Mail certificate under 37 C.F.R. 1.10. An office action is mailed on the date indicated in the Office action." Notice of April 20, 1992 (1138 O.G. 37-41, 39).*

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**NOTE:** "An action on the merits means an action which treats the patentability of the claims in an application, as opposed to only formal or procedural requirements. An action on the merits would, for example, contain a rejection or indication of allowability of a claim or claims rather than just a restriction requirements (37 C.F.R. 1.142) or just a requirement for additional fees to have a claim considered (37 C.F.R. 1.16(d)). Thus, if an application was filed on Jan. 1 and the first Office action on the merits was not mailed until six months later on July 1, the examiner would be required to consider any proper information disclosure statement filed prior to July 1." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

**WARNING:** "A petition for suspension of action to allow applicant time to submit an information disclosure statement will be denied as failing to present good and sufficient reasons, since 37 C.F.R. 1.97 provides adequate recourse for the timely submission of prior art for consideration by the examiner." Notice of July 6, 1992 (1141 O.G. 63).

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SIGNATURE OF PRACTITIONER

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Makoto TSUDA, et al  
Serial No.: 10/676,289 Group No.: 1645  
Filed: October 1, 2003 Examiner.:  
For: SCREENING METHOD OF DRUG FOR TREATMENT OF NEUROPATHIC PAIN

Attorney Docket No.: U 014843-4

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Applicant calls the Examiner's attention to the references listed on the attached Form PTO-1449. Copies of the references are also attached.

**CERTIFICATION UNDER 37 C.F.R. 1.8(a) and 1.10\***

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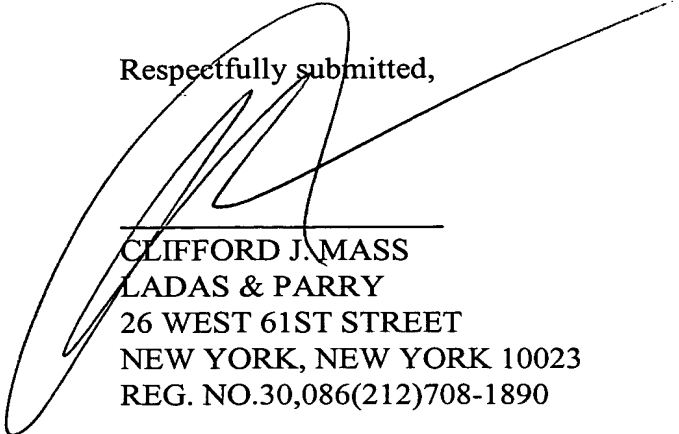
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Respectfully submitted,



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FORM PTO-1449

U. S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICE

ATTY. DOCKET NO.

SERIAL NO.

U 014843-4

10/676,289

INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT

APPLICANT

MAKOTO TSUDA ET AL.

FILING DATE

GROUP

10/01/2003

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## REFERENCE DESIGNATION

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	FILING DATE IF APPROPRIATE
AA				

## FOREIGN PATENT DOCUMENTS

	DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION	
				YES	NO
AB	99/55901	11/1999	WO		
AC	97/41222	11/1997	WO		
AD	95/33048	12/1995	WO		

## OTHER ART (Including Author, Title, Date, Pertinent Dates, Etc.)

AE	Tsuda, Makoto et al. "P2X <sub>4</sub> receptors induced in spinal microglia gate tactile allodynia after nerve injury", <i>Nature</i> , (2003), 424: 778-783
AF	Woolf, Clifford J. and Richard J. Mannion. "Neuropathic pain: aetiology, symptoms, mechanisms, and management", <i>The Lancet</i> , (1999), 353: 1959-1964
AG	Woolf, Clifford J. and Michael W. Salter. "Neuronal Plasticity: Increasing the Gain in Pain", <i>Science</i> , (2000), 288: 1765-1768
AH	Bo, Xuenong, et al. "A P2X purinoceptor cDNA conferring a novel pharmacological profile", <i>FEBS Letters</i> , (1995), 375: 129-133
AI	Buell, G. et al. "An antagonist-sensitive P <sub>2x</sub> receptor expressed in epithelia and brain", <i>The EMBO Journal</i> , (1996), 15(1): 55-62
AJ	Séguéla, Philippe et al. "A Novel Neuronal P <sub>2x</sub> ATP receptor Ion Channel with Widespread Distribution in the Brain", <i>The Journal of Neuroscience</i> , (1996), 16(2): 448-455
AK	Soto, Florentina et al. "P2X <sub>4</sub> : An ATP-activated ionotropic receptor cloned from rat brain", <i>Proc. Natl. Acad. Sci. USA</i> , (1996), 93: 3684-3688
AL	Wang, Chang-Zheng, et al. "Cloning and Pharmacological Characterization of a Fourth P2X Receptor Subtype Widely Expressed in Brain and Peripheral Tissues Including Various Endocrine Tissues", <i>Biochem. Biophys. Res. Commun.</i> , (1996), 220: 196-202
AM	Khakh, Baljit, S. et al. "International Union of Pharmacology. XXIV. Current Status of the Nomenclature and Properties of P2X Receptors and Their Subunits", <i>Pharmacological Reviews</i> , (2001), 53: 107-118
AN	Kim, Sun Ho and Jin Mo Chung. "An experimental model for peripheral neuropathy produced by segmental spinal nerve ligation in the rat", <i>Pain</i> , (1992), 50: 355-363

EXAMINER

DATE CONSIDERED

EXAMINER:

Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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U. S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICEINFORMATION DISCLOSURE  
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	AC					
	AD					

## OTHER ART (Including Author, Title, Date, Pertinent Dates, Etc.)

AE	Virginio, Caterina et al. "Trinitrophenyl-Substituted Nucleotides Are Potent Antagonists Selective for P2X <sub>1</sub> , P2X <sub>3</sub> , and Heteromeric P2X <sub>2/3</sub> Receptors", <i>Molecular Pharmacology</i> , (1998), 53: 969-973
AF	Tsuda, Makoto et al. "Evidence for the involvement of spinal endogenous Atp and P2X receptors in nociceptive responses caused by formalin and capsaicin in mice", <i>British J. Pharmacology</i> , (1999), 128: 1497-1504
AG	Zheng, Ji-Hong and Jun Chen. "Modulatory roles of the adenosine triphosphate P2x-purinoceptor in generation of the persistent nociception induced by subcutaneous bee venom injection in the conscious rat", <i>Neuroscience Letters</i> , (2000), 278: 41-44
AH	Tsuda, Makoto et al. "In vivo pathway of thermal hyperalgesia by intrathecal administration of $\alpha,\beta$ -methylene ATP in mouse spinal cord: Involvement of the glutamate-NMDA receptor system", <i>Brit. J. Pharmacol.</i> , (1999), 127:449-456
AI	Honore, P. et al. "Murine models of inflammatory, neuropathic and cancer pain each generates a unique set of neurochemical changes in the spinal cord and sensory neurons", <i>Neuroscience</i> , (2000), 98(3): 585-598
AJ	Aldskogius, H. and Elena N. Kozlova. "Central neuron-glia and glial-glia interactions following axon injury", <i>Progress in Neurobiology</i> , (1998), 55: 1-26
AK	Sawynok, Jana et al. "ATP release from dorsal spinal cord synaptosomes: characterization and neuronal origin", <i>Brain Research</i> , (1993), 610: 32-38
AL	Li, Ping, Calejesan, Amelita A. and Min Zhuo. "ATP P <sub>2x</sub> Receptors and Sensory Synaptic Transmission Between Primary Afferent Fibers and Spinal Dorsal Horn Neurons in Rats", <i>J. Neurophysiology</i> , (1998), 80: 3356-3360
AM	Nakatsuka, Terumasa and Jianguo G. Gu. "Atp P2X Receptor-Mediated Enhancement of Glutamate Release and Evoked EPSCs in Dorsal Horn Neurons of the Rat Spinal Cord", <i>J. Neuroscience</i> , (2001), 21(17): 6522-6531
AN	Bardoni, Rita et al. "ATP P <sub>2x</sub> Receptors Mediate Fast Synaptic Transmission in the Dorsal Horn of the Rat Spinal Cord", <i>J. Neuroscience</i> , (1997), 17(14): 5297-5304

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AE	Jo, Young-Hwan and Rémy Schlichter. "Synaptic corelease of ATP and GABA in cultured spinal neurons", <i>Nature Neuroscience</i> , (1999), 2(3): 241-245
AF	Fam, S.R., Gallagher, C.J. and M.W. Salter. "P2Y <sub>1</sub> Purinoceptor-Mediated Ca <sup>2+</sup> Signaling and Ca <sup>2+</sup> Wave Propagation in Dorsal Spinal Cord Astrocytes", <i>J. Neuroscience</i> , (2000), 20(8): 2800-2808
AG	Inoue, Kazuhide. "Microglial Activation by Purines and Pyrimidines", <i>Glia</i> , (2002), 40:156-163
AH	Hanisch, Uwe-Karsten. "Microglia as a Source and Target of Cytokines", <i>Glia</i> , (2002), 40: 140-155
AI	Vitkovic, L., Bockaert, J. and Claude Jacque. "'Inflammatory' Cytokines: Neuromodulators in Normal Brain?", <i>Journal of Neurochemistry</i> , (2000), 74: 457-471
AJ	Nakajima, Kazuyuki and Shinichi Kohsaka. "Functional roles of microglia in the brain", <i>Neuroscience Research</i> , (1993), 17: 187-203
AK	Carson, Monica J. "Microglia as Liaisons Between the Immune and Central Nervous Systems: Functional Implications for Multiple Sclerosis", <i>Glia</i> , (2002), 40: 218-231
AL	Eikelenboom, P. et al. "Neuroinflammation in Alzheimer's Disease and Prion Disease", <i>Glia</i> , (2002), 40: 232-239
AM	Nakajima, Kazuyuki, et al. "Identification of Elastase as a Secretory Protease from Cultured Rat Microglia", <i>Journal of Neurochemistry</i> , (1992), 58: 1401-1408
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